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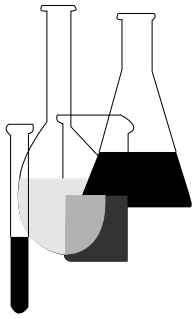
Ecological Effects Test Guidelines

OPPTS 850.4300 Terrestrial Plants Field Study, Tier III



“Public Draft”

INTRODUCTION

This guideline is one of a series of test guidelines that have been developed by the Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency for use in the testing of pesticides and toxic substances, and the development of test data that must be submitted to the Agency for review under Federal regulations.

The Office of Prevention, Pesticides and Toxic Substances (OPPTS) has developed this guideline through a process of harmonization that blended the testing guidance and requirements that existed in the Office of Pollution Prevention and Toxics (OPPT) and appeared in Title 40, Chapter I, Subchapter R of the Code of Federal Regulations (CFR), the Office of Pesticide Programs (OPP) which appeared in publications of the National Technical Information Service (NTIS) and the guidelines published by the Organization for Economic Cooperation and Development (OECD).

The purpose of harmonizing these guidelines into a single set of OPPTS guidelines is to minimize variations among the testing procedures that must be performed to meet the data requirements of the U. S. Environmental Protection Agency under the Toxic Substances Control Act (15 U.S.C. 2601) and the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136, *et seq.*).

Public Draft Access Information: This draft guideline is part of a series of related harmonized guidelines that need to be considered as a unit. *For copies:* These guidelines are available electronically from the EPA Public Access Gopher (gopher.epa.gov) under the heading ‘‘Environmental Test Methods and Guidelines’’ or in paper by contacting the OPP Public Docket at (703) 305–5805 or by e-mail: guidelines@epamail.epa.gov.

To Submit Comments: Interested persons are invited to submit comments. By mail: Public Docket and Freedom of Information Section, Office of Pesticide Programs, Field Operations Division (7506C), Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. In person: bring to: Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. Comments may also be submitted electronically by sending electronic mail (e-mail) to: guidelines@epamail.epa.gov.

Final Guideline Release: This guideline is available from the U.S. Government Printing Office, Washington, DC 20402 on *The Federal Bulletin Board*. By modem dial 202–512–1387, telnet and ftp: fedbbs.access.gpo.gov (IP 162.140.64.19), or call 202–512–0135 for disks or paper copies. This guideline is also available electronically in ASCII and PDF (portable document format) from the EPA Public Access Gopher (gopher.epa.gov) under the heading ‘‘Environmental Test Methods and Guidelines.’’

OPPTS 850.4300 Terrestrial plants field study, Tier III.

(a) **Scope**—(1) **Applicability.** This guideline is intended to meet testing requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136, *et seq.*).

(2) **Background.** The source material used in developing this harmonized OPPTS test guideline is OPP 124–1 Terrestrial Field Testing (Pesticide Assessment Guidelines, Subdivision J—Hazard Evaluation; Nontarget Plants) EPA report 540/09-82-020, 1982.

(3) **Test objective.** This guideline should be used in conjunction with OPPTS guideline 850.4000, Background—Nontarget plant testing, which provides general information and overall guidance for the nontarget plants test guidelines.

(i) **General.** (A) Terrestrial field testing studies are designed to provide phytotoxicity data on a pesticide. These phytotoxicity data are needed to evaluate the level of pesticide exposure to nontarget terrestrial plants and to assess the impact of pesticides on endangered and threatened plants as noted under the Endangered Species Act. Where a phytotoxic effect is noted in one or more plants, additional terrestrial field testing studies may be required. These data are required by 40 CFR 158.150 to support the registration of any pesticide intended for outdoor use under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended.

(B) Pesticides with outdoor use patterns that do not readily release the pesticide to the environment do not have to be evaluated using this phytotoxicity test. These use patterns include tree injection, subsurface soil applications, recapture systems, wick applications, and swimming pool uses. If any of these use patterns do readily expose nontarget plants to the pesticide, as through vapors, the pesticide phytotoxicity potential may need to be evaluated.

(ii) **Objective of the terrestrial field testing Tier III test.** (A) The objective of the Tier III terrestrial field testing study is to determine if a pesticide exerts a detrimental effect to plants during critical stages in their development. The test is performed on species from a cross-section of the nontarget terrestrial plant population. This is a multiple dose test designed to evaluate the phytotoxic effects of the pesticide over a wide range of anticipated pesticide quantities as may be found in the environment.

(B) The Tier III terrestrial nontarget plant phytotoxicity field studies are only required if greater than 25 percent adverse effects on plant growth for terrestrial plants are expected to occur when the product is used as directed by the label (the estimated environmental concentration exceeds the EC25 terrestrial value.

(C) The Tier III tests are expected to provide information on detrimental effects to plants during critical stages of development. The typical end-use product (TEP) is used to assess effects on a broader range of nontarget plant species in a number of geographical areas.

(b) **Test standards.** In addition to the general test standards set forth in OPPTS 850.4000, the test standards for this guideline are the same as those listed in OPPTS 850.4100, with the following modifications:

(1) **Test substance.** The test substance shouldl be the end-use product or a representative end-use product from the same major formulation category for that general use pattern. Examples of major formulation categories are: Wettable powders, emulsifiable concentrates, and granulars. (If the manufacturing-use product is usually formulated into end-use products comprising two or more major formulation categories, a separate study must be performed with a typical end-use product for each category). The test substance used should contain the highest percentage of active ingredient (AI) and/or be the most widely used (total pounds AI).

(2) **Application levels.** The dosages tested should be the same as those employed in the Tier III test, OPPTS 850.4225.

(3) **Species.** (i) Representatives of the following plant groups are to be tested, subject to the limitations of paragraph (b)(2)(iii) of this guideline:

(A) *Dicotyledonae* (dicots), representatives of three families.

(B) *Monocotyledonae* (monocots), representatives of three families.

(C) Vascular *Cryptogamae* (ferns and allies), representatives of two families.

(D) *Bryophyta* (mosses) or *Hepatophyta* (liverworts), one representative (for wetland use patterns only).

(E) *Gymnospermae* (conifers), one representative.

(ii) Plant species used for testing Tiers I and II can be used to satisfy the monocot or dicot test plant requirements of this guideline.

(iii) If any of the plant groups are not likely to be exposed to the pesticide under normal conditions of use, testing of such groups is not required. Justification for elimination of a test species or group should be included in the test report.

(iv) Additional plant species may be required if the general selectivity of the pesticide cannot be readily identified.

(4) **Test conditions.** Plants are to be grown under field-use conditions similar to those of the natural habitat of the plants in nature.

(5) **Duration.** The test duration should be of sufficient length to assess multiple applications directed by the label. Observations should continue for the entire life cycle of the test plants with observations every 2 to 4 weeks.

(6) **Season of application.** The test substance is to be applied over a period of time or season according to the proposed label instructions.

(7) **Test locations.** The pesticide should be tested in those geographic locations where it is expected to be used, as based on proposed label use sites. Where important species diversity and physiographic differences occur within a region of intended application, regional testing may be inadequate, and testing at a more specific region or biome level may be required. United States regional areas of potential testing include: Northeastern temperate deciduous, Southeastern temperate deciduous, Northern grassland (prairie), Southern grassland (prairie), Northwestern (and Alaskan) conifer forest and high desert, Southwestern chaparral Mediterranean and low desert, and Hawaiian and Caribbean tropical regions.

(c) **Reporting.** In addition to the information required in OPPTS 850.4000 and 850.4100, the test report should include the test conditions employed (including the soil and environmental conditions) and the determination of the 50 percent detrimental effect level.

(d) **Data reporting.** (1) The registrant's report on terrestrial field testing studies should include all information necessary to provide:

(i) A complete and accurate description of the field treatments and procedures.

(ii) Sampling data and phytotoxicity rating.

(iii) Data on storage of the plant material, if so performed.

(iv) Results of any chemical analysis of the plant material.

(v) Reporting of the data, rating system, and statistical analysis.

(vi) Quality control measures/precautions taken to ensure the fidelity of the operations.

(2) Each laboratory/greenhouse/small field plot terrestrial field testing report should include the following information:

(i) **General information.** (A) Cooperator or researcher (name and address), test location (county and state; country, if outside of the United States), and date of study.

(B) Name (and signature), title, organization, address, and telephone number of the persons responsible for planning/supervising/monitoring and, for field plot studies, applying the pesticide.

(C) Trial identification number.

(D) Quality assurance indicating: Control measures/precautions followed to ensure the fidelity of the phytotoxicity determinations, record-keeping procedures and availability of logbooks, skill of the laboratory personnel. status of the field and supporting laboratory equipment; degree of adherence to good laboratory practices; and degree of adherence to good agricultural practices in maintaining healthy plants.

(E) Other information the registrant considers appropriate and relevant to provide a complete and thorough description of the test procedures and results.

(ii) **Test substance (pesticide).** (A) Identification of the test pesticide AI including chemical name, common name (ANSI, BSI, ISO, WSSA), and company developmental/experimental name.

(B) AI percentage in the end-use product or representative end-use product from the same major formulation category for that general use pattern.

(C) Dose rates in terms of AI per area of land or of leaf (if leaf-area-index is provided).

(D) Dose rates in terms of less than the maximum label rate with dosages in a geometrical progression of no more than twofold and with subtoxic (<EC50 level) and nontoxic (no-observable-effect level) concentrations.

(E) Method of application including equipment type (nozzles, orifices, pressures).

(F) Number and timing of applications.

(iii) **Plant species.** (A) Identification of the plant species used. Representatives of the following plant groups should be used:

(*1*) *Dicotyledonae* (dicots), three families.

(*2*) *Monocotyledonae* (monocots), three families.

(*3*) Vascular *Cryptogamae* (ferns and allies), two families.

(*4*) *Bryophyta* (mosses) or *Hepatohyta* family (liverworts), (wetland use patterns only).

(*5*) *Gymnospermae* (conifers)—one representative.

(B) Identify the cultivars of the plant species used, where possible.

(C) List the number of replicates and the number of plants per replicate per dose.

(D) Identification of the date of planting, date of pesticide application, and date of phytotoxicity rating or harvest.

(iv) **Site of the test.** (A) Site description of the terrestrial field testing study such as a grassland, forested area, fallow field, tilled field.

(B) Location of the test sites that represent the general regional areas of potential usage: Northeastern temperate deciduous, Southeastern temperate deciduous, Northern grassland (cool prairie), Southern grassland (warm prairie), Northwestern (and Alaskan) conifer forest and high desert, Southwestern chaparral Mediterranean and low desert, and Hawaiian and Caribbean semitropical and tropical regions.

(C) Climatological data during the test (records of applicable conditions for the type of site, i.e., temperature, thermoperiod, rainfall or watering regime, light regime—intensity and quality, relative humidity, wind speed).

(D) Field lay-out (for field plots), e.g., size and number of control and experimental plots;.number of plants per plot/unit area.

(E) Population density of seeds or plants.

(F) Cultural practices such as cultivation and irrigation.

(G) Substrate characteristics of the sites (name/designation of soil type and its physical and chemical properties, including pH and percent organic matter, presence and depth of fragipan or shallow bedrock, etc.).

(v) **Results.** (A) Phytotoxicity rating (including a description of the rating system) for each plant or group of plants (population) in the test.

(B) Weight, height or other growth parameters that may have been measured to ascertain toxic effects of the pesticide upon the plants.

(C) Statistical analysis of the results including environmental or effective concentration (EC) values.

(vi) **Evaluation.** Determination as to whether additional phytotoxicity testing will be necessary to characterize the phytotoxic nature of the chemical.

(e) **References.** The following references should be consulted for additional background material on this test guideline.

(1) Little, T.M. and F.J. Hills. Agricultural Experimentation - Design and Analysis. Wiley, NY (1978).

(2) Truelove, B., ed. Research Methods in Weed Science. Southern Weed Science Society., Auburn, AL. Auburn Printing (1977).

(3) Ratch, H. and J.S. Fletcher. Plant Reproduction and/or Life Cycle Testing. In EPA Publ. EPA/600/9-91/041, Plant Tier Testing: A Workshop to Evaluate Nontarget Plant Testing in Subdivision J Pesticide Guidelines, Nov. 29-Dec. 1, 1990, ERL, Corvallis, OR. pp. 80–89 (1991).

(4) Pfleeger, T. Impact of Airborne Pesticides on Natural Plant Communities. In EPA Publ. EPA/600/9-91/041, Plant Tier Testing: A Workshop to Evaluate Nontarget Plant Testing in Subdivision J Pesticide Guidelines, Nov. 29-Dec. 1, 1990, ERL, Corvallis, OR. pp. 108-123 (1991).